

House Study Bill 228 - Introduced

HOUSE FILE _____

BY (PROPOSED COMMITTEE
ON COMMERCE BILL BY
CHAIRPERSON LUNDGREN)

A BILL FOR

- 1 An Act relating to pharmacy benefits managers, pharmacies, and
- 2 prescription drug benefits, and including applicability
- 3 provisions.
- 4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. Section 505.26, subsection 1, paragraph b, Code
2 2021, is amended to read as follows:

3 b. "*Pharmacy benefits manager*" means the same as defined in
4 section ~~510B.1~~ 510C.1.

5 Sec. 2. Section 507B.4, subsection 2, Code 2021, is amended
6 by adding the following new paragraph:

7 NEW PARAGRAPH. t. *Pharmacy benefits managers.* Any
8 violation of chapter 510B by a pharmacy benefits manager.

9 Sec. 3. Section 510B.1, Code 2021, is amended by striking
10 the section and inserting in lieu thereof the following:

11 **510B.1 Definitions.**

12 As used in this chapter, unless the context otherwise
13 requires:

14 1. "*Clean claim*" means a claim that has no defect or
15 impropriety, including a lack of any required substantiating
16 documentation, or other circumstances requiring special
17 treatment, that prevents timely payment from being made on the
18 claim.

19 2. "*Commissioner*" means the commissioner of insurance.

20 3. "*Cost-sharing*" means any coverage limit, copayment,
21 coinsurance, deductible, or other out-of-pocket expense
22 obligation imposed by a health benefit plan on a covered
23 person.

24 4. "*Covered person*" means a policyholder, subscriber, or
25 other person participating in a health benefit plan that has
26 a prescription drug benefit managed by a pharmacy benefits
27 manager.

28 5. "*Health benefit plan*" means the same as defined in
29 section 514J.102.

30 6. "*Health care professional*" means the same as defined in
31 section 514J.102.

32 7. "*Health carrier*" means the same as defined in section
33 514J.102.

34 8. "*Maximum allowable cost*" means the maximum amount that a
35 pharmacy will be reimbursed by a pharmacy benefits manager or a

1 health carrier for a generic drug, brand-name drug, biologic
2 product, or other prescription drug, and that may include any
3 of the following:

- 4 *a.* Average acquisition cost.
- 5 *b.* National average acquisition cost.
- 6 *c.* Average manufacturer price.
- 7 *d.* Average wholesale price.
- 8 *e.* Brand effective rate.
- 9 *f.* Generic effective rate.
- 10 *g.* Discount indexing.
- 11 *h.* Federal upper limits.
- 12 *i.* Wholesale acquisition cost.
- 13 *j.* Any other term used by a pharmacy benefits manager or a
14 health carrier to establish reimbursement rates for a pharmacy.
- 15 9. "*Maximum allowable cost list*" means a list of
16 prescription drugs that includes the maximum allowable cost
17 for each prescription drug and that is used, directly or
18 indirectly, by a pharmacy benefits manager.
- 19 10. "*Pharmacy*" means the same as defined in section 155A.3.
- 20 11. "*Pharmacy acquisition cost*" means the cost to a pharmacy
21 for a prescription drug as invoiced by a wholesale distributor.
- 22 12. "*Pharmacy benefits manager*" means the same as defined
23 in section 510C.1.
- 24 13. "*Pharmacy benefits manager affiliate*" means a pharmacy or
25 a pharmacist that directly or indirectly through one or more
26 intermediaries, owns or controls, is owned and controlled by,
27 or is under common ownership or control of, a pharmacy benefits
28 manager.
- 29 14. "*Pharmacy network*" or "*network*" means pharmacies that
30 have contracted with a pharmacy benefits manager to dispense
31 or sell prescription drugs to covered persons of a health
32 benefit plan for which the pharmacy benefits manager manages
33 the prescription drug benefit.
- 34 15. "*Prescription drug*" means the same as defined in section
35 155A.3.

1 16. *"Prescription drug benefit"* means the same as defined
2 in section 510C.1.

3 17. *"Prescription drug order"* means the same as defined in
4 section 155A.3.

5 18. *"Wholesale distributor"* means the same as defined in
6 section 155A.3.

7 Sec. 4. Section 510B.2, Code 2021, is amended to read as
8 follows:

9 **510B.2 Certification as a third-party administrator required.**

10 A pharmacy benefits manager doing business in this state
11 shall obtain a certificate of registration as a third-party
12 administrator ~~under chapter 510~~ pursuant to section 510.21, and
13 the provisions relating to a third-party administrator pursuant
14 to chapter 510 shall apply to a pharmacy benefits manager.

15 Sec. 5. Section 510B.4, Code 2021, is amended to read as
16 follows:

17 **510B.4 Performance of duties — good faith — conflict of**
18 **interest.**

19 1. A pharmacy benefits manager shall ~~perform the pharmacy~~
20 ~~benefits manager's duties exercising~~ exercise good faith and
21 fair dealing in the performance of ~~its~~ the pharmacy benefits
22 manager's contractual obligations toward ~~the covered entity a~~
23 health carrier.

24 2. A pharmacy benefits manager shall notify ~~the covered~~
25 entity a health carrier in writing of any activity, policy,
26 practice ownership interest, or affiliation of the pharmacy
27 benefits manager that presents any conflict of interest.

28 Sec. 6. Section 510B.5, Code 2021, is amended to read as
29 follows:

30 **510B.5 Contacting covered individual persons — requirements.**

31 A pharmacy benefits manager, unless authorized pursuant to
32 the terms of its contract with a ~~covered entity~~ health carrier,
33 shall not contact any covered ~~individual person~~ without
34 the express written permission of the ~~covered entity~~ health
35 carrier.

1 Sec. 7. Section 510B.6, Code 2021, is amended to read as
2 follows:

3 **510B.6 ~~Dispensing of substitute~~ Substitute prescription drug**
4 **~~for prescribed drug~~ drugs.**

5 1. The following provisions shall apply ~~when if~~ a pharmacy
6 benefits manager requests the dispensing of a substitute
7 prescription drug for a ~~prescribed drug to~~ prescribed for a
8 ~~covered individual person by the covered person's health care~~
9 professional:

10 a. The pharmacy benefits manager may request the
11 substitution of a lower priced generic and therapeutically
12 equivalent prescription drug for a higher priced ~~prescribed~~
13 prescription drug.

14 b. If the substitute prescription drug's net cost to the
15 ~~covered individual person or covered entity to the health~~
16 carrier exceeds the cost of the ~~prescribed~~ prescription drug
17 originally prescribed for the covered person, the substitution
18 shall be made only for medical reasons that benefit the
19 ~~covered individual person as determined by the covered person's~~
20 prescribing health care professional.

21 2. A pharmacy benefits manager shall obtain the approval of
22 the prescribing ~~practitioner~~ health care professional prior to
23 requesting any substitution under [this section](#).

24 3. A pharmacy benefits manager shall not substitute an
25 equivalent prescription drug contrary to a prescription drug
26 order that prohibits a substitution.

27 Sec. 8. Section 510B.7, Code 2021, is amended by striking
28 the section and inserting in lieu thereof the following:

29 **510B.7 Pharmacy networks.**

30 1. A pharmacy located in the state shall not be prohibited
31 from participating in a pharmacy network provided that the
32 pharmacy accepts the same terms and conditions as the pharmacy
33 benefits manager imposes on the pharmacies in the network.

34 2. A pharmacy benefits manager shall not assess, charge, or
35 collect any form of remuneration that passes from a pharmacy

1 or a pharmacist in a pharmacy network to the pharmacy benefits
2 manager including but not limited to claim processing fees,
3 performance-based fees, network participation fees, or
4 accreditation fees.

5 Sec. 9. Section 510B.8, Code 2021, is amended by striking
6 the section and inserting in lieu thereof the following:

7 **510B.8 Prescription drugs — point of sale.**

8 1. A covered person shall not be required to make a
9 cost-sharing payment at the point of sale for a prescription
10 drug in an amount that exceeds the maximum allowable cost for
11 that drug at the pharmacy at which the covered person fills the
12 covered person's prescription drug order.

13 2. A pharmacy benefits manager shall not prohibit a pharmacy
14 from disclosing the availability of a lower-cost prescription
15 drug option to a covered person, or from selling a lower-cost
16 prescription drug option to a covered person.

17 3. Any amount paid by a covered person for a prescription
18 drug purchased pursuant to this section shall be applied to any
19 deductible imposed by the covered person's health benefit plan
20 in accordance with the health benefit plan coverage documents.

21 4. A covered person shall not be prohibited from filling
22 a prescription drug order at any pharmacy located in the
23 state provided that the pharmacy accepts the same terms and
24 conditions as the pharmacy benefits manager imposes on at least
25 one of the pharmacy networks that the pharmacy benefits manager
26 has established in the state.

27 5. A pharmacy benefits manager shall not impose different
28 cost-sharing or additional fees on a covered person based on
29 the pharmacy at which the covered person fills the covered
30 person's prescription drug order.

31 6. A pharmacy may decline to dispense a prescription drug to
32 a covered person if, as a result of the maximum allowable cost
33 list to which the pharmacy is subject, the pharmacy will be
34 reimbursed less for the prescription drug than the pharmacy's
35 acquisition cost.

1 Sec. 10. NEW SECTION. **510B.8A Maximum allowable cost lists.**
2 1. Prior to placement of a particular prescription drug on a
3 maximum allowable cost list, a pharmacy benefits manager shall
4 ensure that all of the following requirements are met:
5 *a.* The particular prescription drug must be listed as
6 therapeutically and pharmaceutically equivalent in the most
7 recent edition of the publication entitled "Approved Drug
8 Products with Therapeutic Equivalence Evaluations", published
9 by the United States food and drug administration, otherwise
10 known as the orange book.
11 *b.* The particular prescription drug must not be obsolete or
12 temporarily unavailable.
13 *c.* The particular prescription drug must be available for
14 purchase, without limitations, by all pharmacies in the state
15 from a national or regional wholesale distributor that is
16 licensed in the state.
17 2. For each maximum allowable cost list that a pharmacy
18 benefits manager uses in the state, the pharmacy benefits
19 manager shall do all of the following:
20 *a.* Provide each pharmacy in a pharmacy network reasonable
21 access to the maximum allowable cost list to which the pharmacy
22 is subject.
23 *b.* Update the maximum allowable cost list within seven
24 calendar days from the date of an increase of ten percent or
25 more in the pharmacy acquisition cost of a prescription drug on
26 the list by one or more wholesale distributors doing business
27 in the state.
28 *c.* Update the maximum allowable cost list within seven
29 calendar days from the date of a change in the methodology, or
30 a change in the value of a variable applied in the methodology,
31 on which the maximum allowable cost list is based.
32 *d.* Provide a reasonable process for each pharmacy in a
33 pharmacy network to receive prompt notice of all changes to the
34 maximum allowable cost list to which the pharmacy is subject.
35 Sec. 11. NEW SECTION. **510B.8B Pharmacy benefits manager**

1 **affiliates — reimbursement.**

2 A pharmacy benefits manager shall not reimburse any pharmacy
3 located in the state in an amount less than the amount that
4 the pharmacy benefits manager reimburses a pharmacy benefits
5 manager affiliate for dispensing the same prescription drug
6 as dispensed by the pharmacy. The reimbursement amount shall
7 be calculated on a per unit basis based on the same generic
8 product identifier or generic code number.

9 Sec. 12. NEW SECTION. 510B.8C **Clean claims.**

10 After the date of receipt of a clean claim submitted by a
11 pharmacy in a pharmacy network, a pharmacy benefits manager
12 shall not retroactively reduce payment on the claim, either
13 directly or indirectly, except if the claim is found not to be
14 a clean claim during the course of a routine audit.

15 Sec. 13. NEW SECTION. 510B.8D **Appeals and disputes.**

16 1. A pharmacy benefits manager shall provide a reasonable
17 process to allow a pharmacy to appeal a maximum allowable cost,
18 or a reimbursement made under a maximum allowable cost list,
19 for a specific prescription drug for any of the following
20 reasons:

21 a. The pharmacy benefits manager violated section 510B.8A.

22 b. The maximum allowable cost is below the pharmacy
23 acquisition cost.

24 2. The appeal process must include all of the following:

25 a. A dedicated telephone number at which a pharmacy may
26 contact the pharmacy benefits manager and speak directly with
27 an individual involved in the appeal process.

28 b. A dedicated electronic mail address or internet site for
29 the purpose of submitting an appeal directly to the pharmacy
30 benefits manager.

31 c. A period of at least seven business days after the date
32 of a pharmacy's initial submission of a clean claim during
33 which the pharmacy may initiate an appeal.

34 3. A pharmacy benefits manager shall respond to an appeal
35 within seven business days after the date on which the pharmacy

1 benefits manager receives the appeal.

2 *a.* If the pharmacy benefits manager grants a pharmacy's
3 appeal, the pharmacy benefits manager shall do all of the
4 following:

5 (1) Adjust the maximum allowable cost of the prescription
6 drug that is the subject of the appeal and provide the national
7 drug code number that the adjustment is based on to the
8 appealing pharmacy.

9 (2) Permit the appealing pharmacy to reverse and rebill the
10 claim that is the subject of the appeal.

11 (3) Make the adjustment pursuant to subparagraph (1)
12 applicable to each pharmacy in the state subject to the same
13 maximum allowable cost list as the appealing pharmacy.

14 *b.* If the pharmacy benefits manager denies a pharmacy's
15 appeal, the pharmacy benefits manager shall do all of the
16 following:

17 (1) Provide the appealing pharmacy the national drug
18 code number and the name of a wholesale distributor licensed
19 pursuant to section 155A.17 from which the pharmacy can obtain
20 the prescription drug at or below the maximum allowable cost.

21 (2) If the national drug code number provided by the
22 pharmacy benefits manager pursuant to subparagraph (1) is
23 not available below the pharmacy acquisition cost from the
24 wholesale distributor from whom the pharmacy purchases the
25 majority of its prescription drugs for resale, the pharmacy
26 benefits manager shall adjust the maximum allowable cost list
27 above the appealing pharmacy's pharmacy acquisition cost, and
28 permit the pharmacy to reverse and rebill each claim affected
29 by the pharmacy's inability to procure the prescription drug
30 at a cost that is equal to or less than the previously appealed
31 maximum allowable cost.

32 Sec. 14. Section 510B.9, Code 2021, is amended to read as
33 follows:

34 **510B.9 ~~Submission, approval, and use of prior~~ Prior**
35 **authorization form.**

1 A pharmacy benefits manager shall ~~file with and have~~
2 ~~approved by the commissioner a single prior authorization~~
3 ~~form as provided in section 505.26 comply with all applicable~~
4 ~~prior authorization requirements pursuant to section 505.26.~~
5 ~~A pharmacy benefits manager shall use the single prior~~
6 ~~authorization form as provided in section 505.26.~~

7 Sec. 15. Section 510B.10, Code 2021, is amended by striking
8 the section and inserting in lieu thereof the following:

9 **510B.10 Enforcement.**

10 1. The commissioner shall take any enforcement action under
11 the commissioner's authority to enforce compliance with this
12 chapter.

13 2. After notice and hearing, the commissioner may impose any
14 sanctions pursuant to section 507B.7, and may suspend or revoke
15 a pharmacy benefits manager's certificate of registration as
16 a third-party administrator upon a finding that the pharmacy
17 benefits manager violated this chapter, or any applicable
18 requirements pertaining to third-party administrators under
19 chapter 510.

20 3. A pharmacy benefits manager, as an agent or vendor of a
21 health carrier, is subject to the commissioner's authority to
22 conduct an examination pursuant to chapter 507. The procedures
23 set forth in chapter 507 regarding examination reports shall
24 apply to an examination of a pharmacy benefits manager under
25 this chapter.

26 4. A pharmacy benefits manager is subject to the
27 commissioner's authority to conduct a proceeding pursuant
28 to chapter 507B. The procedures set forth in chapter 507B
29 regarding proceedings shall apply to a proceeding related to a
30 pharmacy benefits manager under this chapter.

31 5. A pharmacy benefits manager is subject to the
32 commissioner's authority to conduct an examination, audit,
33 or inspection pursuant to chapter 510 for third-party
34 administrators. The procedures set forth in chapter 510 for
35 third-party administrators shall apply to an examination,

1 audit, or inspection of a pharmacy benefits manager under this
2 chapter.

3 6. If the commissioner conducts an examination of a pharmacy
4 benefits manager under chapter 507; a proceeding under chapter
5 507B; or an examination, audit, or inspection under chapter
6 510, all information received from the pharmacy benefits
7 manager, and all notes, work papers, or other documents related
8 to the examination, proceeding, audit, or inspection shall
9 be confidential records pursuant to chapter 22 and shall be
10 accorded the same confidentiality as notes, work papers,
11 investigatory materials, or other documents related to the
12 examination of an insurer as provided in section 507.14.

13 7. A violation of this chapter shall be an unfair or
14 deceptive act or practice in the business of insurance pursuant
15 to section 507B.4, subsection 3.

16 Sec. 16. NEW SECTION. 510B.11 Rules.

17 The commissioner shall adopt rules pursuant to chapter 17A
18 to administer this chapter.

19 Sec. 17. NEW SECTION. 510B.12 Severability.

20 If a provision of this chapter or its application to any
21 person or circumstance is held invalid, the invalidity does
22 not affect other provisions or applications of this chapter
23 which can be given effect without the invalid provision or
24 application, and to this end the provisions of this chapter are
25 severable.

26 Sec. 18. REPEAL. Section 510B.3, Code 2021, is repealed.

27 Sec. 19. APPLICABILITY. This Act applies to pharmacy
28 benefits managers that manage a health carrier's prescription
29 drug benefit in the state on or after the effective date of
30 this Act.

31 EXPLANATION

32 The inclusion of this explanation does not constitute agreement with
33 the explanation's substance by the members of the general assembly.

34 This bill relates to pharmacy benefits managers, pharmacies,
35 and prescription drug benefits.

1 The bill requires a pharmacy benefits manager (PBM) to allow
2 a pharmacy located in the state to participate in a pharmacy
3 network (network) provided that the pharmacy accepts the same
4 terms and conditions as the PBM imposes on the pharmacies
5 in the network. "Pharmacy benefits manager" is defined in
6 the bill as a person who, pursuant to a contract or other
7 relationship with a health carrier, either directly or through
8 an intermediary, manages a prescription drug benefit provided
9 by the health carrier. "Pharmacy network", "pharmacy",
10 "prescription drug benefit", and "health carrier" are also
11 defined in the bill.

12 The bill prohibits a PBM from assessing, charging, or
13 collecting any form of remuneration that passes from a pharmacy
14 in the network to the PBM including but not limited to claim
15 processing fees, performance-based fees, network participation
16 fees, or accreditation fees.

17 The bill prohibits a covered person from being required
18 to make a cost-sharing payment at the point-of-sale for a
19 prescription drug (drug) in an amount that exceeds the maximum
20 allowable cost (MAC) for that drug. The bill defines the
21 "maximum allowable cost" as the maximum amount that a pharmacy
22 will be reimbursed by a PBM or a health carrier for a generic
23 drug, brand-name drug, biologic product, or other drug and
24 that may include the average or national average acquisition
25 cost; the average manufacturer price; the average wholesale
26 price; the brand or generic effective rate; discount indexing;
27 federal upper limits; wholesale acquisition cost; or any other
28 term used by a PBM or health carrier to establish reimbursement
29 rates for a pharmacy. "Covered person" is defined in the bill.

30 A PBM cannot prohibit a pharmacy from disclosing the
31 availability of a lower-cost drug option to a covered person,
32 or from selling a lower-cost drug option to a covered person.
33 The bill requires that any amount paid by a covered person
34 for a drug in the circumstances detailed in the bill must
35 be applied to any deductible imposed by the covered person's

1 health benefit plan in accordance with the plan's coverage
2 documents. Under the bill, a covered person cannot be
3 prohibited from filling a drug order at any pharmacy located in
4 the state if the pharmacy accepts the same terms and conditions
5 as the PBM imposes on at least one of the pharmacy networks
6 that the PBM has established in the state. A PBM cannot
7 impose different cost-sharing or additional fees on a covered
8 person based on the pharmacy at which a covered person fills
9 their prescription. The bill allows a pharmacy to decline
10 to dispense a drug to a covered person if, as a result of
11 the maximum allowable cost list (MACL) to which the pharmacy
12 is subject, the pharmacy will be reimbursed less than the
13 pharmacy's acquisition cost. "Pharmacy acquisition cost" is
14 defined in the bill. "Maximum allowable cost list" is defined
15 in the bill as a list of prescription drugs that includes the
16 MAC for each drug and that is used, directly or indirectly,
17 by a PBM. "Pharmacy acquisition cost" is also defined in the
18 bill.

19 The bill requires that prior to placement of a particular
20 drug on a MACL, a PBM must ensure that the drug is listed as
21 therapeutically and pharmaceutically equivalent in the most
22 recent edition of the "Approved Drug Products with Therapeutic
23 Equivalence Evaluations", published by the United States
24 food and drug administration; the drug cannot be obsolete or
25 temporarily unavailable; and the drug must be available for
26 purchase by all pharmacies in the state from a national or
27 regional wholesale distributor (distributor) that is licensed
28 in the state. "Wholesale distributor" is defined in the bill.

29 The bill requires a PBM to provide each pharmacy in a
30 network reasonable access to the MACL to which the pharmacy is
31 subject, and to update each MACL within seven calendar days
32 from the date of an increase of 10 percent or more in the
33 pharmacy acquisition cost of a drug by one or more distributors
34 doing business in the state. The PBM must also update a MACL
35 within seven calendar days from the date of a change in the

1 methodology, or a change in a value of a variable applied in
2 the methodology, on which the MACL is based. The PBM is also
3 required to provide a process for each pharmacy in a network to
4 receive prompt notice of all changes to a MACL.

5 The bill prohibits a PBM from reimbursing a pharmacy located
6 in the state in an amount less than the amount that the PBM
7 reimburses a PBM affiliate for dispensing the same drug as the
8 pharmacy. "Pharmacy benefits manager affiliate" is defined in
9 the bill.

10 The bill provides that after the date of receipt of a clean
11 claim submitted by a pharmacy, a PBM cannot retroactively
12 reduce payment on the claim, either directly or indirectly,
13 except if the claim is found not to be a clean claim during the
14 course of a routine audit. "Clean claim" is defined in the
15 bill.

16 The bill requires a PBM to provide a process for pharmacies
17 to appeal a MAC, or a reimbursement made under a MACL. The
18 requirements for the appeal process are detailed in the bill.

19 The commissioner of insurance (commissioner) is required to
20 take any enforcement action under the commissioner's authority
21 to enforce compliance with the bill. After notice and hearing,
22 the commissioner may impose any sanctions pursuant to Code
23 section 507B.7, and may suspend or revoke a PBM's certificate
24 of registration as a third-party administrator (administrator)
25 upon a finding that the PBM violated any requirements of
26 the bill, or any applicable requirements pertaining to
27 administrators under Code chapter 510.

28 A PBM is subject to the commissioner's authority to conduct
29 an examination pursuant to Code chapter 507 and a proceeding
30 pursuant to Code chapter 507B. A PBM is also subject to
31 the commissioner's authority to conduct an examination,
32 audit, or inspection pursuant to Code chapter 510. If the
33 commissioner conducts an examination, a proceeding, an audit,
34 or an inspection, all information received from the PBM, and
35 all documents related to the examination, proceeding, audit, or

1 inspection are confidential records pursuant to Code chapter
2 22.

3 A violation of the bill is an unfair or deceptive act or
4 practice in the business of insurance pursuant to Code section
5 507B.4.

6 The bill requires the commissioner to adopt rules to
7 administer the bill.

8 If a provision of the bill or its application to any person
9 or circumstance is held invalid, the invalidity does not affect
10 other provisions or applications of the bill that can be given
11 effect without the invalid provision or application.

12 The bill make conforming changes to Code sections 510B.2,
13 510B.4, 510B.5, 510B.6, and 510B.9.

14 The bill repeals Code section 510B.3 which is replaced in
15 large part by new Code section 510B.10 (enforcement).

16 The bill applies to PBMs that manage a health carrier's
17 prescription drug benefit in the state on or after the
18 effective date of the bill.